

REMARKS

In the Office Action mailed September 30, 2005, Claims 1, and 3-7 are pending in the present application. Claim 2 has been canceled and claims 8-24 have been withdrawn. Each of these claims was rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,197,828 to Jerussi et al. (hereinafter 'the 828 patent').

By the present amendment, Claim 1 has been amended to include several new elements. The claim now requires that the therapeutically-effective amount of pharmaceutical be uniformly distributed and be selected from the group of pharmaceutical agents consisting of antibiotics, antiinfectives, cardiovascular therapeutics, gastrointestinal agents, pschotropics, and mixtures thereof. Support for this amendment can be found in originally filed claim 2 as well as in the published original specification ¶¶ 45, and 94. Claim 1 has further been amended so as to incorporate a specific group of compressible material for use in the pharmaceutical product. Support for this amendment can be found in ¶¶ 69-70 of the published application. An additional limitation was amended into claim 1 such that the lubricating material is present in an amount of up to 5% by weight of the product and the lubricating material was selected from the group consisting of fats, emulsifiers, waxes, magnesium stearate, calcium stearate, talc, starches, silicon dioxide, and mixtures thereof. Support for this amendment can be found in the published specification in ¶ 71. Claim 1 was also amended so as to require that the product be strong enough to withstand mechanical pressure and release the pharmaceutical in the gastrointestinal tract of the subject to which the product is administered. Support for this amendment can be found in ¶ 94.

The above-recited rejection will be addressed below. It is respectfully requested that the Examiner further consider the application in view of these remarks.

The Present Invention

Before discussing each of the rejections a brief summary of the present invention is made. The present invention is drawn to pharmaceutical product in a compressed tablet or caplet form having a diameter and length of from about 1 mm to about 7mm each. The pharmaceutical product comprises a therapeutically effective amount of a uniformly distributed pharmaceutical, at least one compressible material,

and at least one lubricating material. The lubricating material can be present in the product in amounts of up to 5% and the product as a whole must be able to withstand mechanical pressure and release the pharmaceutical in the gastrointestinal tract of the subject.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1-7, under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. '828 patent. The Applicant respectfully submits that these claims are patentable over the cited reference for the reasons set forth below, and that the rejection should be withdrawn.

As has been discussed in the previous responses, the '828 patent discloses methods of preparing, and compositions comprising derivatives of (+) venlafaxine. The dosage forms may include tablets, caplets, troches, lozenges, dispersions, suspensions, suppositories, ointments cataplasms, pastes, powders, dressings, creams, plasters, solutions, capsules, soft elastic gelatin capsules, and patches. The only teaching specifically regarding compressed tablet or caplet formulations is found in Example 7, beginning at the bottom of column 26 and running through column 27. Table III sets for the formulations for the compressed tables. For ease of reference, Table III of the '828 patent has been recreated below. It is noted that the final two rows of the recreated table are added and contain the total weight of each capsule and the percent of lubricant (lubricant as used in the pending claim 1) per capsule.

TABLE III of '828 patent

Compressed Tablet Unit Dosage Forms			
Component	25 mg capsule	50 mg capsule	100 mg capsule
(+)-O-desmethyl-venlafaxine	25	50	100
Microcrystalline Cellulose	90.0	90.0	90
Pre-gelatinized Starch	100.3	97.8	82.8
Croscarmellous	7.0	7.0	7.0
Magnesium Stearate	0.2	0.2	0.2
Total Weight	222.5	245	280
% Lubricant*	45.17%	40.0%	29.64%

* Calculated by dividing the sum of the weights of Magnesium Stearate and the pre-gelatinized starch by the total weight of each formulation.

As shown in the table above, the compressed oral formulations of '828 patent contain a pharmaceutical in the form of venlafaxine, a compressible material in the form of microcrystalline cellulose, and lubricating materials in the forms of pre-gelatinized starch and magnesium stearate. However, there is no teaching in the '828 patent that the lubricating material be limited to "up to about 5%" of the total weight of the pharmaceutical product, as required by claim 1 of the pending application. As shown in the table above, the compressed oral formulations taught by the '828 patent contain at least 29% by weight of a lubricating material as defined in claim 1 of the present invention which is contrary to the teachings of the teachings of the present claims and application. Additionally, there is no teaching or suggestion in the '828 patent that limiting the amount of the lubricating material to 5% or less would be desirable. Therefore the '828 patent does not teach each and every element of the claimed invention.

The formulations of the '828 patent further fail to teach a tablet which is compressible into a diameter and length of from about 1mm to about 7mm. The Examiner has previously stated that size of the pharmaceutical product alone would not be sufficient to render the present invention patentable. The Applicant does not argue that the size alone is what renders the present invention patentable, but rather the formulation itself, which renders the pharmaceutical product capable of being compressed into the claimed sizes. As stated in the previously submitted affidavit, which is resubmitted herewith, the formulations of the '828 patent are not capable of being compressed into tablets or caplets as required by the claims.

As provided in the Declaration, applicant tried but was unable to make a tablet of 9mm size by following the '828 patent disclosure of columns 26 and 27. The dry blend powder could not be compressed and remained as a powder. Applicant then conducted three additional experiments to improve upon the '828 patent disclosure so that a pharmaceutically acceptable tablet of 9mm size could be produced. In experiment 2, applicant tried to granulate the product in an effort to improve compressibility. Again, applicant could not compress the granules into a tablet. In Experiment 3, applicant used talc to improve compressibility and hardness. However the product was still unsatisfactory. Applicant then conducted Experiment 4 whereby more talc was used. In Experiment 4, the product was compressible and of suitable hardness. Applicant studied the '828 patent with regard to the formulation used in

Experiment 4 and determined that there was teaching of such a formulation. The formulation of Experiment 4 did not exhibit a controlled release profile, specifically because 90% or more of the drug was released within the first hour.

As the '828 patent fails to teach a pharmaceutical formulation with 5% or less of a lubricating material and a formulation which can be compressed into a tablet or caplet with a size of from about 1mm to about 7mm, it fails to teach each and every element of the pending claims. As such, it is respectfully requested that the rejection be withdrawn and the pending claims allowed.

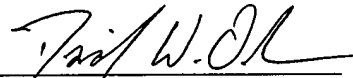
CONCLUSION

In view of the foregoing, Applicants believe that pending claims 1-7 present allowable subject matter and allowance thereof is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 29~~th~~ day of March, 2006.

Respectfully submitted,



David W. Osborne
Attorney for Applicant
Registration No. 44,989

Of:

THORPE NORTH & WESTERN, LLP
8180 South 700 East, Suite 200
Sandy, Utah 84070
(801) 566-6633

STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

An in-person interview was held with Examiner Fubara and Applicant's representatives, Dr. Phanesh Koneru and Mr. David Osborne on February 23, 2006. During the interview the testing procedures carried out and presented in Applicant's declaration filed as part of the previous office action response were discussed. It was also discussed that it had been discovered that a page of the declaration had been inadvertently missing, potentially causing the Examiner's previous confusion.

It was agreed that Applicant would file a new copy of the complete declaration with the next office action response. Further it was agreed that Applicant would amend Claim 1 to place the size range of the claimed tablet in the preamble, and recite some of the additional claim components in markush lists of preferred agents.